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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUANG, EVELYN MEI	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,301	SCHNUTE ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-49 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-49 are pending.

Duplicate Claims

2. Claim 38 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. The recitation of the use of the compound of claim 1 in claim 38 fails to further limit the scope of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A method for inhibiting a herpesviral DNA polymerase reaches out to as yet unidentified activities/conditions/disorders, a full description of which are not found in the specification.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the specification is only enabling for using the inventive compound for treating atherosclerosis or restenosis resulting from herpesviral infection or for inhibiting a herpesviral DNA polymerase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

a. *Nature of the invention.*

The instant invention is drawn to a thienopyridine compound for treating atherosclerosis or restenosis and for inhibiting herpes viral DNA polymerase.

b. *State of the prior art and the level of the skill in the art.*

The etiology of atherosclerosis is controversial in that multiple factors play a role as either causative or aggravating agents. At the time of the invention, beta lipoproteins are suggested to be basically responsible for the disease (The Merck Manual, 11th Edition, page 213). One of ordinary skill in the art therefore would have no basis to use an anti-herpesviral agent to treat atherosclerosis or restenosis caused by or aggravated by agents unrelated to herpesviral infection.

The level of the skill in the antiviral art is high.

c. *Predictability/unpredictability of the art.*

The high degree of unpredictability is well recognized in the antiviral art. A slight change in the structure of the compound would drastically change its HCMV polymerase activities as evidenced in the structurally similar compounds (Vaillancourt et al, Bioorganic & Medicinal Chemistry Letters. 2000, 10: 2079-2081, page 2080, Tables 1-5).

d. *Amount of guidance/working examples.*

The preparation of example compounds has been described. The procedure for assessing the HCMV polymerase inhibitory activity is described on pages 25-26, and the results are described for the example compounds on page 27 of the specification. No in vivo procedures are described.

e. *Breadth of the claims.*

Applicant's assertion that the inventive compounds would be effective in treating atherosclerosis or restenosis does not commensurate with the scope of the objective enablement, especially in view of the fact that herpesviral infection is not the only cause of atherosclerosis, the high degree of unpredictability in the antiviral art and the working examples limited only to inhibition of HCMV polymerase (paragraphs b, c, d above).

f. *Quantitation of undue experimentation.*

Since insufficient guidance and teaching have been provided by the specification (paragraphs c-e above), one of ordinary skill in the art, even with high level of skill, is unable to use the instant compound as claimed without undue experimentation except for treating atherosclerosis or restenosis resulting from herpesviral infection.

5. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The court holds that claims directed to mediating a biological pathway are devoid identifiable utility and are therefore not useful. Unless the pathway at issue is critical to treating some condition and the pathway modification and disease treatment are inexorably linked, such pathway modification is devoid of utility. The instant claim directed to a mechanism of inhibiting herpes viral DNA polymerase without the end result would therefore have no practical utlity unless the inhibition of herpes viral DNA polymerase and the treatment of infections by herpes virus are inexorably linked. Since the claims as recited embrace any degree of inhibition of herpes viral DNA polymerase, which may or may not inexorably linked to the treatment of herpes viral infection, the scope of the claims is therefore not commensurate with that of the objective enablement, especially in view of the absence of a full written description of the as yet unidentified conditions/activities/disorders which the recited mechanism reaches out to. One of ordinary skill in the art therefore would not be able to use the inventive compound as claimed without undue experimentation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-5, 8, 10-14, 21, 25-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnute (6239142, available as prior art under 102(b)).

Schnute generically discloses an anti-herpesviral 4-oxo-4, 7-dihydrothienopyridine carboxamide compound, and the optically active isomers thereof (columns 1-3; column 5, lines 1-2), which encompasses the instant. The process of making is also described. Specific compounds are described (column 53, Examples 39, 40; column 76, claim 21, compound (5), (6)).

The prior art example compound has a phenyl whereas the instant has a pyridinyl or pyrimidinyl as R4. Schnute, however, teaches that phenyl within the meaning of aryl, and quinolinyl, pyridinyl, pyrazinyl or pyramidinyl within the meaning of heteroaryl are optional choices (column 68, claim 1, lines 1-16; column 5, lines 45-53)

One of ordinary skill in the art would be motivated to replace the phenyl of Schnute's example with the alternative, quinolinyl, pyridinyl, pyrazinyl or pyrimidinyl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

Schnute's Example 35 (column 50; column 73, claim 18, compound (23)) has a 2-hydroxymethyl whereas the compound of instant claim 49 has a 2-chloromethyl.

However, chloromethyl and hydroxymethyl are optional choices (columns 67-68, claim 1, definition of R3, (b), (i), (p)). One of ordinary skill in the art would be motivated to replace the hydroxy of Schnute's example with the alternative chloro to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

8. Claims 1-5, 8, 10-14, 21, 25-41, 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnute (6239142) in view of King FD (Medicinal Chemistry. Principles and Practice. 1994. The Royal Society of Chemistry. Pages 206-208).

Schnute generically discloses an anti-herpesviral 4-oxo-4, 7-dihydrothienopyridine carboxamide compound, and the optically active isomers thereof (columns 1-3; column 5, lines 1-2), which encompasses the instant. Specific compounds are described (column 53, Examples 39, 40; column 76, claim 21, compound (5), (6)).

The prior art example compound has a phenyl whereas the instant has a pyridinyl as R4. Phenyl and pyridinyl are art-recognized isosteric equivalents (King, page 208). Furthermore, Schnute teaches that phenyl within the meaning of aryl, and pyridinyl within the meaning of heteroaryl are optional choices (column 68, claim 1, lines 1-16; column 5, lines 45-53)

One of ordinary skill in the art would be motivated to replace the phenyl of Schnute's example with the alternative, isosteric pyridinyl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-5, 8, 10-14, 21, 25-43, 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 23-32 of U.S. Patent No. 6239142. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons set forth in paragraphs 7, 8 above.

11. Claims 1-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/649202 in view of Schnute (6239142).

The copending compound has a phenyl whereas the instant as a pyridinyl or pyrimidinyl as R4. Schnute teaches that phenyl within the meaning of aryl, and pyridinyl, pyrazinyl or pyrimidinyl within the meaning of heteroaryl are optional choices (column 68, claim 1, lines 1-16; column 5, lines 45-53). One of ordinary skill in the art would be motivated to replace the copending phenyl with the alternative, pyridinyl, pyrazinyl or pyrimidinyl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

The instant quinolinyl as R4 is attached to the N-ethyl via the pyridine ring of the quinolinyl whereas the copending quinolinyl as R4 is bonded to the N-ethyl via the benzene ring of the quinolinyl. The copending compound is therefore a positional isomer of the instant. Schnute, however, teaches that the position of attachment of the heteroaryl is an optional choice (column 70, lines 8-15). One of ordinary skill in the art would be motivated to prepare the positional isomer of the copending compound as taught by Schnute to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/649208 in view of Schnute (6239142).

The copending compound has a 5-membered heteroaryl whereas the instant as a 6-membered heteroaryl as R4. Schnute, however, teaches that the 5-membered heteroaryl and the 6-membered heteroaryl are optional choices (column 68, claim 1, lines 1-16; column 5, lines 45-53). One of ordinary skill in the art would be motivated to replace the 5-membered heteroaryl with the alternative 6-membered heteroaryl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang
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Art Unit 1625